



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 21 1999

NDA 20-255/S-005

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Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Route 120 & Wilson Road
Round Lake, IL 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated February 17, 1999, received February 22, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutamine HCl in 5% Dextrose Injection in Plastic Container.

This supplemental new drug application provides for final printed labeling replacing the present **INDICATIONS AND USAGE** section with the following text:

Dobutamine in 5% Dextrose Injection is indicated when parental therapy is necessary for inotropic support in the short-term treatment of patients with cardiac decompensation due to depressed contractility resulting either from organic heart disease or from cardiac surgical procedures. Experience with intravenous dobutamine in controlled trials does not extend beyond 48 hours of repeated boluses and/or continuous infusions.

Whether given orally, continuously intravenously, or intermittently intravenously, neither dobutamine nor any other cyclic-AMP-dependent inotrope has been shown in controlled trials to be safe or effective in the long-term treatment of congestive heart failure. In controlled trials of chronic oral therapy with various such agents, symptoms were not consistently alleviated, and the cyclic-AMP-dependent inotropes were consistently associated with increased risks of hospitalization and death. Patients with NYHA Class IV symptoms appeared to be at particular risk.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your February 17, 1999 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5334

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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